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**VIA ELECTRONIC MAIL**

RE: Required Freedom of Information Act Protections for Endocrine Disrupter Screening Program Tier 1 Data Evaluation Records

Dear Director Housenger and Dr. Dix:

First, thank you again, Jack, for taking the time to meet with CropLife America (CLA) leadership on March 2 along with your team. We very much appreciated hearing from your office on a variety of important issues. As you know, CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American growers. CLA is dedicated to supporting responsible stewardship of our members' products to promote the health and well-being of people and the environment, and to promote increasingly responsible, science-driven legislation and regulation of pesticides.

After the meeting on March 2, I had the opportunity to speak briefly with Bill Jordan regarding the Environmental Protection Agency (EPA)'s intention to publish on its website, in connection with its Endocrine Disruptor Screening Program (EDSP), Data Evaluation Records for List 1 Tier 1 compounds (Tier 1 DERs). I am writing now to relate my understanding of that conversation, provide additional background on CLA's position on the topic, and to request a letter confirming EPA's intentions.

CLA appreciates that EPA recognizes the critical role of plant protection products in protecting global health and food safety and quality. CLA also appreciates the leadership role EPA has taken both in the United States and globally in promoting the use of scientific principles, such as relevant hazard and exposure data, in identifying plant protection products that could be found to act as endocrine disruptors.

As an interested stakeholder, CLA recognizes transparency as critical to public understanding and approval of the regulatory process. As Bill and I discussed, however, CLA is concerned that should EPA grant unrestricted public internet access to all content that may be contained in the Tier 1 DERs, such access may not provide the protections to confidential business information and proprietary data (collectively, Protected Material) Congressionally mandated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Freedom of Information Act (FOIA). The loss of these protections could potentially not only be found to be in violation of these federal laws, but could also create a disincentive for investing in new products on the fear that EPA would not protect these investments from market competitors. Alternatively, should EPA follow its own statutes and regulations regarding the protection of Protected Material, and allow the submitters of Protected Material the opportunity to redact that information from DERs, the resulting "blacklined" document on EPA websites could confuse the public about the nature of the redacted material. A far better approach would be to follow long-standing EPA practice and treat Tier 1 DERs like other DERs, subject to the protections of FIFRA § 10(g), discussed more fully below.

A. EDSP Background Information

As you know, the EDSP uses a tiered approach for determining whether a substance may have an effect in humans that is similar to an effect produced by naturally occurring estrogen, androgen, or thyroid hormones. The core elements of the EDSP are Tier 1 Screening and Tier 2 testing and hazard assessment. Tier 1 screening consists of a battery of screening assays intended to identify substances with the potential to interact with estrogen, androgen, or thyroid hormone systems. Currently fifty-two active and inert pesticide chemicals are undergoing Tier 1 screening.

EPA has developed a set of protocols to be used in evaluating registrant data for the Tier 1 assay battery. As we understand these protocols, EPA personnel will develop a DER for each of the

individual assays in the battery. The information and conclusions in the Tier 1 DERs will then be reviewed collectively to determine whether a substance warrants Tier 2 testing. Whether or not information in a Tier 1 DER materially contributes to EPA's determination will depend on the substance being screened, the specific DER and the results contained therein. DERs, by their very nature, contain registrant-submitted Protected Material. EPA provides for the protection of Protected Material through processes laid out at 40 C.F.R. § 2.

B. Tier 1 DERs are Entitled to FIFRA § 10(g) and FOIA Protections

As EPA is aware, strategic development and innovation of new plant protection products benefits both human health and the environment. As EPA is also aware, pesticide manufacturers must devote significant time and resources to develop new products. If EPA cannot assure manufacturers that their Protected Material will, in fact, be protected from market competitors, these manufacturers will likely lose any competitive incentive to create new, softer chemistries. Congress, recognizing the importance of promoting new plant protection products, enacted measures to ensure Protected Material does not reach the hands of market competitors. These measures are found in both FIFRA and FOIA. EPA has also enacted its own regulations to implement both statutes. These regulations set out the process for requesting documents containing Protected Material and EPA's restrictions on the release of such information. 40 C.F.R. § 2.201 *et seq.*

FIFRA § 10(g)(1) protects registrant data from oversees and multinational competitors.[1] It states, in relevant part:

> The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering for sale to any such business or entity or its agents or employees to be delivered to such business or entity or its agents or employees.

[1] *See also* FIFRA § 10(f).

Further, FIFRA § 10(g)(2) states:

> The Administrator shall maintain records of the names of persons to whom data are disclosed under [§ 10(g)] and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliations of such persons.

Congress's protections of Protected Material in FIFRA are consistent with much broader Congressional intent to preserve research and commercial incentives through the protection of such information. FOIA specifically allows a federal agency to exempt from disclosure documents containing Protected Material. *See* FOIA, Exemptions 3 & 4. As mentioned above, EPA has also promulgated its own regulations to implement these protections, and utilizes them regularly. These regulations set out a detailed process that EPA must follow when it receives a request for documents that may contain Protected Material. 40 C.F.R. § 2.201 *et seq.*; 40 C.F.R. § 2.307. These procedures, among other things, require that when EPA seeks a document that may contain Protected Material, it must allow the submitting organization the opportunity to designate those portions it considers protected. 40 C.F.R. § 2.203. Should EPA then receive a FOIA request for that document, EPA must provide notice of the request and provide the submitting organization the opportunity to comment before any final determination on protection is made. 40 C.F.R. § 2.204. If EPA determines that information data submitters have marked as Protected Material is not confidential, the data submitter has the right to seek judicial review before EPA releases any contested information. 40 C.F.R. § 2.205.

CLA members are familiar with the processes EPA has put in place for the protection of their Protected Material. This process is regularly followed when public requests are made for the contents of DERs. Indeed, EPA's guidance specifically states that DERs are "likely" to contain Protected Material, subject to protection under federal law. http://www2.epa.gov/foia/limitations-disclosure-information-under-pesticide-law. The simple uploading of full DERs to a public website does not appear to offer those protections, and to that extent, does not appear to be consistent with FIFRA or FOIA. Per my conversation with Bill on March 2, it is CLA's understanding that EPA will afford submitters' data in Tier 1 DERs with the protections afforded by FIFRA, FOIA and EPA's regulations governing Protected Material.

Recent European Union (EU) judicial interpretations of Aurhaus Treaty disclosure requirements emphasize the importance of EPA's protection of its data submitters' Protected Material when that information may be shared with EU regulators. Under current EU interpretation of the Treaty's disclosure requirements, EU regulators may provide no protection for Protected Material. While CLA strongly supports the sharing of scientific expertise and experience between EPA and EU regulators, this cannot be done in violation of federal law requiring EPA to protect data submitters' Protected Material.

C. Redacted Studies on a Website Could Confuse the Public

As discussed above, and as EPA has recognized in other contexts, DERs frequently contain Protected Material that require redaction before the document can be publicly disclosed. In the context of the EDSP, the resulting "blacklined" Tier 1 DER would certainly not provide a complete picture of the information underlying the DER. Seen on a website, this redaction could be misinterpreted in any number of ways. Also, unlike DERs in other contexts, Tier 1 DERs do not contain final conclusions and may not even materially contribute to a Tier 1 determination. In this context, EPA may wish to consider exempting these DERs from public disclosure altogether as an early stage of its deliberative process. *See* FOIA, Exemption 5. One purpose of FOIA Exemption 5's deliberative process privilege is to "protect against public confusion that might result from disclosure of reasons and rationales that were not in fact ultimately the grounds for an agency action." Department of Justice Guide to FOIA. http://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption5_1.pdf. EPA should consider withholding entirely, as other agencies have done, such preliminary scientific data. *See e.g. Chem. Mfrs. Ass'n v. Consumer Prod. Safety Comm'n*, 600 F. Supp. 114, 117-118 (D.D.C. 1984) (finding that ongoing regulatory process would be subject to "delay and disruption" if preliminary scientific data associated with chemical studies were disclosed); *AFGE v. HHS*, 63 F. Supp.2d 104, 108 (D. Mass. 1999) (finding that agencies should not release predecisional documents because the release "could cause harm by providing the public with erroneous information").

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As discussed above, both CLA members and EPA recognize that DERs often contain Protected Material that data submitters have a right to protect. Given that understanding, the data submitters whose data will be the subject of the Tier 1 DERs expect the right to review the draft DERs for potential Protected Material in the manner outlined in EPA's regulations. Please notify CLA and the data submitters immediately if EPA intends not to afford the data submitters this opportunity.

CLA supports the desire of EPA to build public understanding and support for its EDSP program through the sharing of its analyses. However, this cannot be done in violation of federal law protecting Protected Material. When this protection could result in blacklined DERs available on an EPA website, the public could misinterpret those redactions. EPA should consider these individual Tier 1 DERs to be preliminary reflections of its deliberative process, and exempt them from public disclosure altogether, or make them available under the well-established procedures of FIFRA § 10(g), within which redactions of Protected Material are well-understood or can be readily explained.

In light of these considerations, CLA would like to gain a better understanding of how EPA plans to meet its obligations under FIFRA and FOIA to protect CLA members' Protected Material in EDSP

Tier 1 DERs. CLA, therefore, requests that EPA provide it with a written response to this correspondence no later than April 15, 2015. If you have any questions or would like to also discuss this issue further, please do not hesitate to contact me at 202-872-3895 or rlattimore@croplifeamerica.org.

Sincerely,

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